

AD _____

Award Number: DAMD17-98-C-8048

TITLE: The Prospective Army Coronary Calcium (PAAC) Study

PRINCIPAL INVESTIGATOR: Allen J. Taylor, LTC, MC

CONTRACTING ORGANIZATION: Systems Assessment and Research,
Incorporated
Lanham, Maryland 20706-2925

REPORT DATE: September 2003

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
Distribution Unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

20040324 028

REPORT DOCUMENTATION PAGE			Form Approved OMB No. 074-0188	
Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302, and to the Office of Management and Budget, Paperwork Reduction Project (0704-0188), Washington, DC 20503				
1. AGENCY USE ONLY (Leave blank)		2. REPORT DATE September 2003		3. REPORT TYPE AND DATES COVERED Annual (16 Aug 02-15 Aug 03)
4. TITLE AND SUBTITLE The Prospective Army Coronary Calcium (PAAC) Study			5. FUNDING NUMBERS DAMD17-98-C-8048	
6. AUTHOR(S) Allen J. Taylor, LTC, MC				
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Systems Assessment and Research, Incorporated Lanham, Maryland 20706-2925 E-Mail: allen.taylor@na.amedd.army.mil			8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012			10. SPONSORING / MONITORING AGENCY REPORT NUMBER	
11. SUPPLEMENTARY NOTES				
12a. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited				12b. DISTRIBUTION CODE
13. ABSTRACT (Maximum 200 Words) <p>Electron beam computed tomography (EBCT) is a noninvasive x-ray test like a CAT scan that detects calcium in the arteries of the heart. When calcium deposits are present, they indicate that some build-up of arterial blockages has begun in the arteries. The available evidence on EBCT shows that patients with calcium deposits are more likely to develop heart problems, such as heart attacks. There is controversy, however, because it is not clear whether EBCT is more accurate than traditional risk factor measurements for predicting who is most likely to develop heart disease. Some of the controversy has arisen because EBCT is expensive (about \$500 per test). The test is also very sensitive, possibly too sensitive, meaning that many patients will have arterial abnormalities, but only some will ultimately experience problems with heart disease.</p> <p>Because of its promise and uncertainties, the Army needs to understand whether EBCT is a better way to screen our personnel than our current methods. This study, which will enroll 2000 active duty Army personnel (men and women) between the ages of 40 and 45, will answer 3 important questions about the utility of EBCT as a screening test in our active-duty troops:</p> <ol style="list-style-type: none"> 1. How common is coronary calcium in aged 40 to 45 year old active duty Army personnel? How does the expense and accuracy of an EBCT screening program compare to our current program of risk factor measurements? 2. Does finding coronary calcium on an EBCT provide patients with better information to help guide them to healthier and happier lifestyles compared to our current measurements, like cholesterol? Are patients more motivated to eat right and exercise, for example, when they know they have early arterial blockages? 3. Can we predict who will develop heart disease in the future better using an EBCT scan or a cholesterol measurement? Better predictions about heart disease risk will allow us to more accurately prescribe risk-reducing treatments like cholesterol medicines and aspirin. <p>This study will help the Army understand the full implications of this new test, EBCT, on the cardiovascular health of our active-duty force. This knowledge will help guide the Army's application of this technology within the cardiovascular screening program.</p>				
14. SUBJECT TERMS No subject terms provided.			15. NUMBER OF PAGES 9	
			16. PRICE CODE	
17. SECURITY CLASSIFICATION OF REPORT Unclassified	18. SECURITY CLASSIFICATION OF THIS PAGE Unclassified	19. SECURITY CLASSIFICATION OF ABSTRACT Unclassified	20. LIMITATION OF ABSTRACT Unlimited	

Table of Contents

Cover.....	1
SF 298.....	2
Table of Contents.....	3
Introduction.....	4
Body.....	5
Key Research Accomplishments.....	7
Reportable Outcomes.....	8
Conclusions.....	9
References.....	None
Appendices.....	None

Introduction

The purpose of the Army's cardiovascular screening program, initiated in 1981 and revised in 1989, was to reduce the incidence of sudden cardiac death associated with the mandatory semi-annual Army Physical Fitness Test. Despite mandatory screening for high risk individuals aged 40 years and older over the last decade, it does not appear that cardiovascular screening has had a major impact on sudden cardiac death of the middle aged U.S. Army soldier. This has prompted the Office of the Surgeon General, Department of the Army, to search for other screening tests for asymptomatic individuals. One such possibility is electron beam computed tomography (EBCT), which detects and quantifies coronary atherosclerotic burden in older populations through detection of coronary calcification. Civilian data, derived largely from selected, higher risk, and self-referred populations, are inadequate to assess the wide-scale application of this technology to lower risk individuals. To understand how EBCT might improve cardiovascular screening in the Army, the Prospective Army Coronary Calcium (PACC) study (a large, prospective, single center study) is investigating the relationship between EBCT findings, coronary risk behavior, and cardiovascular events, in young, asymptomatic U.S. Army personnel. This proposal focuses on evidence-based technology integration and preventive medicine. These aims have been endorsed by both the "Military Health Services System 2020 Report" and the Medical Research and Materiel Command "The Role of Technology in Reducing Health Care Costs" (MRMC white paper, October 1996) as major research initiatives for the future of military medicine.

The PACC study is addressing the following objectives:

- 1) To determine the prevalence, extent, and cost implications of the diagnosis of coronary calcification in asymptomatic active-duty military 40- to 45- year-old men and women undergoing routine cardiovascular screening.
- 2) To assess the impact of EBCT results on several dimensions of patient behavior for coronary risk factor modification, and its interaction with the CVSP.
- 3) To establish the relationship between EBCT coronary calcification and cardiovascular events in an unselected, low-risk military population.

Recent literature continues to support the continuation of the current study protocol. The primary aim of this study, to compare EBCT and the Framingham index for their prognostic utility in coronary heart disease, remains unanswered within the current literature.

As of August 1, 2003, 2000 participants have been enrolled in the cohort study (160 since the date of the last APR). This completes the goal of 2000 enrollees per the statement of work. The randomized trial cohort follow up was completed in March 2002 and this study was published in the Journal of the American Medical Association during May , 2003. A total of 58 adverse events have been reported, none that were directly related to participation in the study. Each of these events represent natural history of coronary disease events, or evaluations for possible cardiac symptoms during the telephonic monitoring phase of the study.

The contract to SAR Inc. (employees handle data collection and management for the study) was renewed through MRMC as of August 2001 and is continuing. The contractor is dutifully executing the statement of work, and progress on the project is steady and continuous.

There have been no changes to the protocol during the past year.

Publications during January 2002- August 2003:

1. Taylor AJ, Watkins T, Bell D, Carrow J, Bindeman J, Feuerstein IM, Wong H, Bhattarai S, O'Malley PG. Physical activity promotes a healthy cardiovascular risk factor profile but is unrelated to the presence or extent of subclinical atherosclerosis. *Med Sci Sports Exer*, 2002;34:228-33.
2. Elgin E, Taylor AJ, Feuerstein I, O'Malley PG. The frequency and severity of EBCT "incidentalomas": Implications for coronary calcium screening. *Am J Cardiol* 2002 Sep 1;90(5):543-5.
3. Lee TC, O'Malley PG, Feuerstein IM, Taylor AJ. The prevalence and severity of coronary artery calcification on electron beam computed tomography in black and white subjects. *J Am Coll Cardiol*, 2003;41:39-44.
4. O'Malley PG, Feuerstein IM, Taylor AJ. Impact of electron beam tomography, with or without case management, on motivation, behavioral change, and cardiovascular risk profile: A randomized controlled trial. *JAMA*. 2003;289:2215-2223.
5. Hunt ME, O'Malley PG, Feuerstein I, Taylor AJ. The metabolic "score" predicts subclinical atherosclerosis independent of fasting serum LDL: Evidence supporting inclusion of the

metabolic syndrome as a component within the NCEP ATP III Guidelines. *Coron Artery Dis*, 2003;14:317-322.

6. Taylor AJ, Carrow J, Bell D, Bindeman J, Watkins T, Lehmann T, Bhattarai S, Wong H, O'Malley PG. Validation of the MEDFICTS dietary questionnaire: A clinical tool to assess adherence to American Heart Association dietary fat intake guidelines. *Nutrition Journal*, 2003; 2:4.
7. O'Malley PG, Greenberg BA, Taylor AJ. The cost effectiveness of scanning for coronary calcium: A decision analysis of screening EBCT's downstream costs. *Am Heart J*. In revision.
8. Flynn J, Taylor AJ, Jones DL, O'Malley PG. Correlation between psychological factors and motivation for healthy behavioral change. *Psychosomatics*, submitted.
9. Tofferi JK, Taylor AJ, Feuerstein IM, O'Malley PG. Alcohol intake is not associated with subclinical coronary atherosclerosis. Submitted.
10. Villines TC, Hatzigeorgiou C, Feuerstein I, O'Malley PG, Taylor AJ. Vitamin K intake and coronary calcification. Submitted.

ABSTRACTS

1. Hunt ME, O'Malley PG, Feuerstein I, Taylor AJ. The metabolic "score" predicts subclinical atherosclerosis independent of fasting serum LDL: Evidence supporting inclusion of the metabolic syndrome as a component within the NCEP ATP III Guidelines. *J Am Coll Cardiol* 2002; 39:262A.
2. Lee TC, O'Malley PG, Feuerstein I, Taylor AJ. Ethnicity and calcified atherosclerosis: Can data on coronary calcium be applied evenly across ethnic groups? Results from the Prospective Army Coronary Calcium Project. *J Am Coll Cardiol* 2002; 39:359A.
3. O'Malley PG, Feuerstein IM, Taylor AJ. Anatomic screening with electron beam tomography does not enhance cardiovascular risk reduction in primary prevention: A randomized, double-blind, controlled trial comparing intensive case management to usual care, with or without EBT. *Circulation*, 2002; 106(19):II-743.
4. Bautista L, Taylor AJ, Atwood JE, O'Malley PG. Association between C-reactive protein and hypertension among low cardiovascular risk subjects. *Circulation*, 2003;107 (7): 7001e
5. Villines TC, Hatzigeorgiou C, Feuerstein I, O'Malley PG, Taylor AJ. Vitamin K intake and coronary calcification. *Arterioscler Thromb Vasc Biol* 2003;23:a12
6. Taylor AJ, Bindeman J, Bhattarai S, Tan C, Feuerstein I, O'Malley PG. Family history of premature coronary heart disease and coronary disease risk: Do second degree relatives "count"? *Circulation*, in press.

Key Research Accomplishments:

- Completed SOW goal of enrolling 2000 patients
- Randomized trial (specific aim 2) completed and published
- Continued telephonic follow up of the existing cohort (enrolled to date)

Reportable Outcomes

Presentations and Publications: see above

Conclusions

Enrollment in the cohort study is complete. The study is in its final phases, concentrating on telephonic tracking of the cohort for cardiovascular events. Continued subgroup analyses on questions of interest within the approved dataset are continuing.